DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5468]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration's Adverse Event and Product Experience Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 25, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0291. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA's Adverse Event and Product Experience Reporting Program

OMB Control Number 0910–0291—Revision

This information collection supports FDA laws and regulations governing adverse event reports and product experience reports for FDA-regulated products. The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b, 355, 360i, 360l, 379aa, and 393) and the Public Health Service Act (42 U.S.C. 262) authorize FDA to collect adverse event reports and product experience reports from regulated industry and to monitor the safety of drugs, biologics, medical devices, and dietary supplements. These reporting and recordkeeping requirements are found in FDA regulations, discussed in Agency guidance, and included in Agency forms. Although not all respondents to the information collection are required to submit reports, we encourage voluntary reporting of adverse experiences associated with any FDA-regulated product.

To facilitate both consumer and industry reporting of adverse events and experiences with FDA-regulated products, we developed the MedWatch program. The MedWatch program allows anyone to submit reports to FDA on adverse events, including injuries and/or deaths, as well as other product experiences associated with the products we regulate. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 329, 600, and 803 (21 CFR 310, 314, 600, and 803), and specified in sections 503B, 760, and 761 of the FD&C Act (21 U.S.C. 353b, 379aa, and 379aa–1). Mandatory reporting of adverse events for human cells, tissues, and cellular- and tissue-based products (HCT/Ps) have been codified in Sec. 1271.350 (21 CFR 1271.350). Other postmarketing reporting associated with requirements found in sections 201, 502, 505, and 701 (21 U.S.C. 321, 352, 355, and 371) of the FD&C Act and applicable to certain drug products with and without approved applications are accounted for in OMB control number 0910–0230. Mandatory reporting under 21 CFR part 803, associated with medical device products, using form FDA 3500a, is accounted for in OMB control number 0910–0437.

Since 1993, mandatory adverse event reporting has been supplemented by voluntary reporting by healthcare professionals, patients, and consumers via the MedWatch reporting process. To carry out its responsibilities, the Agency needs to be informed when an adverse event, product problem, error with use of a human medical product, or evidence of therapeutic failure is suspected or identified in clinical use. When FDA receives this information from healthcare professionals, patients, or consumers, the report becomes data that will be used to assess and evaluate the risk associated with the product. FDA will take any necessary action to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

To implement these reporting provisions for FDA-regulated products (except vaccines) during their post-approval and marketed lifetimes, we developed the following three forms, available for download from our website or upon request to the Agency: (1) Form FDA 3500 may be used for voluntary (*i.e.,* not mandated by law or regulation) reporting by healthcare professionals; (2) Form FDA 3500A is used for mandatory reporting (*i.e.,* required by law or regulation); and (3) Form FDA 3500B, available in English and Spanish, is written in plain language and may be used for voluntary reporting (*i.e.,* not mandated by law or regulation) by consumers (*i.e.,* patients and their caregivers). Respondents to the information collection are healthcare professionals, medical care organizations and other user facilities (*e.g.,* extended care facilities, ambulatory surgical centers), consumers, manufacturers of biological, food products including dietary supplements and special nutritional products (*e.g.,* infant formula and medical foods), cosmetics, drug products or medical devices, and importers.

Use of Form FDA 3500, MedWatch—The Safety Information and Adverse Event Reporting Program (Voluntary Reporting)

This voluntary version of the form may be used by health care professionals to submit all reports not mandated by Federal law or regulation. Individual health care professionals are not required by law or regulation to submit reports to the Agency or the manufacturer, with the exception of certain adverse events following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986. Reports for vaccines are not submitted via MedWatch or MedWatch forms but are submitted to the Vaccines Adverse Event Reporting System (VAERS; see *http://vaers.hhs.gov*), which is jointly administered by FDA and the Centers for Disease Control and Prevention.

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required to report medical device-related deaths and serious injuries (accounted for in OMB control number 0910–0437).

Under Federal law and regulation (section 761(b)(1) of the FD&C Act), a

dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Therefore, the Agency depends on the voluntary reporting by healthcare professionals and especially by consumers of suspected serious adverse events and product quality problems associated with the use of dietary supplements. All dietary supplement reports were originally received by the Agency on paper versions of Form FDA 3500 (by mail or fax). Today, electronic reports may be sent to the Agency via an online submission route called the Safety Reporting Portal at *http://www.safetyreporting.fda.gov/*. In that case, the Form FDA 3500 is not used.

Form FDA 3500 may be used to report to the Agency adverse events, product problems, product use errors, and therapeutic failures. The form is provided in both paper and electronic formats. Reporters may mail or fax paper forms to the Agency. A fillable .pdf version of the form is available at *https://www.accessdata.fda.gov/scripts/medwatch/* or electronically submit a report via the MedWatch Online Voluntary Reporting Form at *https://www.accessdata.fda.gov/scripts/medwatch/*.

Reporting using Form FDA 3500 in paper form is supported for drugs, non-vaccine biologicals, medical devices, food products, special nutritional products, cosmetics, and non-prescription human drug products marketed without an approved application, and dietary supplements. Electronic reports for FDA products, may be submitted to the Agency via an online submission route called the Safety Reporting Portal at *http://www.safetyreporting.fda.gov/*.

Electronic reports for tobacco products may be submitted to the Agency via the tobacco questionnaire within the online Safety Reporting Portal at *http://www.safetyreporting.fda.gov/*.

Use of Form FDA 3500A, MedWatch for use by User-Facilities, Importers, Distributors, and Manufacturers (Mandatory Reporting)

Drug and Biological Products

Sections 503B, 505(j), and 704 of the FD&C Act (21 U.S.C. 374) require that important safety information relating to all human prescription drug products be made available to FDA in the event it becomes necessary to take appropriate action to ensure protection of the public health. Mandatory reporting of adverse events for HCT/Ps is codified in Sec. 1271.350. Consistent with statutory requirements, information is required to be submitted electronically and therefore we account for most all reports under OMB control number 0910–0230 to support electronic reporting to our MedWatch program. At the same time, regulations are provided for waivers from the electronic submission requirements and we therefore account for paper-based reporting in this information collection.

Medical Device Products

Section 519 of the FD&C Act (21 U.S.C. 360i) requires manufacturers and importers, of devices intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may by regulation reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Device Act of 1990, signed into law on November 28, 1990, amends section 519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 CFR part 803 (part 803). Part 803 mandates the use of the Form FDA 3500A for reporting to FDA on medical devices. Mandatory reporting associated with medical device products using form FDA 3500A is accounted for in OMB control number 0910–0437.

Dietary Supplements

Section 502(x) in the FD&C Act implements the requirements of The Dietary Supplement and Nonprescription Drug Consumer Protection Act, which became law (Pub. L. 109–462) on December 22, 2006. These requirements apply to manufacturers, packers, and distributors of nonprescription human drug products marketed without an approved application. The law requires reports of serious adverse events to be submitted to the Agency by manufacturers of dietary supplements.

Electronic reports for dietary supplements may be submitted using the Safety Reporting Portal at *http://www.safetyreporting.fda.gov/*. Paper-based dietary supplement reports may be submitted using the MedWatch Form FDA 3500A.

Use of Form FDA 3500B, MedWatch Consumer Voluntary Reporting

This voluntary version of the form may be used by consumers, patients, or caregivers to submit reports not mandated by Federal law or regulation. Individual consumers, patients, or caregivers are not required by law or regulation to submit reports to the Agency or the manufacturer. FDA supports and encourages direct reporting to the Agency by consumers of suspected adverse events and other product problems associated with human medical products, food, dietary supplements, and cosmetic products and invite these respondents to visit our website at *https://www.fda.gov/safety/report-problem-fda* for more information. Since the inception of the MedWatch program in July 1993, the program has been promoting and facilitating voluntary reporting by both the public and healthcare professionals. FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free phone number or the MedWatch internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Pub. L. 107–109).

Section 906 of the FDA Amendments Act amended section 502(n) of the FD&C Act, mandating that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *https://www.fda.gov/medwatch,* or call 1–800–FDA–1088.'' Most private vendors of consumer medication information, the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report ''side effects'' to FDA and provide contact information to permit MedWatch reporting.

Form FDA 3500B, since it was first made available in 2013 was tailored for

consumers and written in plain language in conformance with the Plain Writing Act of 2010 (*https://www.govinfo.gov/content/pkg/PLAW-111publ274/pdf/PLAW-111publ274.pdf*) and has evolved with input from human factors experts, from other regulatory agencies and with extensive input from consumer advocacy groups and the public. It is used to report adverse events, product problems, product use errors and problems after switching from one product maker to another maker to the Agency. The form is available in Spanish at *https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda* and available to upload electronically since 2021 at *https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.spanish* and provided in both paper and electronic formats. Respondents may submit reports by mail or fax paper forms to the Agency or electronically submit a report via the MedWatch Online Voluntary Reporting Form at *https://www.accessdata.fda.gov/scripts/medwatch/*. A fillable.pdf version of the form, available at *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf* may be downloaded, completed, and mailed or faxed to the Agency. Reporting is supported for drugs, non-vaccine biologicals, medical devices, food products, special nutritional products, cosmetics, and non-prescription human drug products marketed without an approved application. The paper form may also be used to submit reports about dietary supplements. Electronic reports for dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal at *http://www.safetyreporting.fda.gov/*.

Use of Form FDA 3800, Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to the FDA. Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances. Food Manufacturers, processors, packers, and holders, researchers, an applicant of an approved drug product or a manufacturer, distributor or packer listed on the label of any marketed drug product, drug manufacturers, sponsors, sponsor-investigators of investigational drugs and biologics, dietary supplement manufacturers, packers, and distributors, tobacco product manufacturers.

Others, including healthcare providers, public health officials, and other professionals, as well as consumers and concerned citizens, may voluntarily submit reports if they encounter safety issues with a product and/or harmful effects that they believe are related to a product.

The information collection includes the following agency forms, available electronically via the Safety Reporting Portal:

Center for Veterinary Medicine—Voluntary reporting of adverse events and product problems involving Pet Food or Livestock Food. Section 1002(b) of the FDAAA directed the Secretary to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. We developed the Pet Food Early Warning System rational questionnaire as a user-friendly data collection tool, as well as a questionnaire for collecting voluntary adverse event reports associated with pet and livestock food. Information collected in these voluntary adverse event reports contribute to CVM's ability to identify adulteration of the pet and livestock food supply and outbreaks of illness associated with pet and livestock food. We use the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses.

Center for Tobacco Products—Voluntary Tobacco Product Health Problem or Product Problem Reports (*i.e.,* Adverse experience reports). Voluntary adverse experience reports have been collected from consumers/concerned citizens and healthcare professionals via the Safety Reporting Portal's (SRP) Tobacco Problem Report (TPR) questionnaire since January 10, 2014, from tobacco product manufacturers via the SRP TPR since June 10, 2016, and from researchers engaged in clinical trials using investigational or legally marketed tobacco products via the SRP Tobacco Investigator Report (TIR) questionnaire since June 10, 2016. For efficiency of Agency operations, we have consolidated activities associated with adverse event reporting previously approved under OMB control number 0910–0879 into this collection.

Mandatory Tobacco Product Health Problem or Product Problem Reports (*i.e.,* Adverse experience reports). On October 5, 2021 (86 FR 55300), FDA published a rule titled ''Premarket Tobacco Product Applications and Recordkeeping Requirements (PMTA)''. The rule establishes regulatory definitions (§ 1114.3) for adverse experience, serious adverse experience and unexpected adverse experience associated with tobacco product use. The Final Rule, in effect since November 4, 2021, requires premarket applicants (manufacturers of new tobacco products) who receive marketing granted orders to report all serious and unexpected adverse experiences associated with the tobacco product (§ 1114.41(a)(2)) that have been reported to the applicant or of which the applicant is aware, to the SRP or in another manner designated by FDA, within 15 calendar days of their awareness.

Proposed Modifications to Existing Forms 3500, 3500A and 3500B

General Changes

The proposed modifications to Form FDA 3500, 3500A and Form FDA 3500B (English and Spanish) reflect changes that will bring the forms into conformation, since the previous authorization in 2022, with current regulations, rules, and guidances. The proposed extension to Form FDA 3500, Form FDA 3500A, and Form FDA 3500B will only have changes in the form instructions to provide clarity of reporting. The proposed changes fall into one of three categories (1) regulatory driven revisions (2) work improvements for the Center and (3) report processing improvements. Formatting modifications are being proposed to several fields to enhance the quality, utility and clarity of the information. We also propose to update the mailing address add mailing address to Attn: MedWatch Program, White Oak Campus, Building 22, G0207, 10903 New Hampshire Ave., Silver Spring, MD 20993.

Changes Proposed for Form FDA 3500

Throughout the form, we propose to:

- add calendar functionality to all date fields for uniformity and standardization of date format.

In the header, we propose to specify the intended reporters at the top of form (*i.e.,* Health Professional Voluntary Reporting).

In Section A, we propose to:

- based on the executive order, Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, signed by President Donald J. Trump on January 20, 2025, revise the Sex field to include two options, Male and Female. and remove the Gender field. combine the Ethnicity (Field A5) and Race (Field A6) fields as

outlined in the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) issued on March 29, 2024. Add new text—''What is your race and/or ethnicity? Select all that apply.'' The data fields include:

- American Indian or Alaska Native
- Asian
- Black or African American
- Hispanic or Latino
- Middle Eastern or North African
- Native Hawaiian or Pacific Islander
- White

In Section B, we propose to:

• re-order the outcomes attributed to adverse events list so that ''Other Serious or Important Medical Events'' appears as the last choice of the outcomes listed in Field B2.

• Add field for reference ranges in the Relevant Test/Laboratory Data section (Field B6)

In Section C, we propose to:

• Add field for Where (*e.g.,* website, pharmacy/store/state of purchase) was the suspect product obtained and When (date) was the suspect product obtained

In section D, we propose to:

• Remove 'This report involves cosmetic, dietary supplement, food/medical food and other.'' Cosmetic will now be captured under the ''Product Type'' section Field D5.)

• add ''Usage Dates'' after ''Treatment Dates/Therapy Dates'' and add ''Usage'' after ''treatment'' and ''Therapy'' in Field D3.

• revise the ''Product Type'' section (Field D5) as follows: (Note: Dietary supplement and Food/medical food selections will be removed. Adverse events involving these products should be submitted through the Safety Reporting Portal)

- Drug or Biologic
  - Brand
  - Generic or Biosimilar
  - Over-the Counter (OTC)
  - Compounded product (by a Pharmacy or an Outsourcing Facility)
- Cosmetic
  - Cosmetic for professional use only
  - Cosmetic sold on a retail basis
- Cannabinoid Hemp Products (such as products containing CBD)
- Other

In section E, we propose to interchange the fields 2a and 2b. ''Procode'' will now appear in field 2a and ''Common Device Name'' will appear in field 2b.

In section G, we propose to add a field ''Packer'' to the list under ''Also Reported to'' in Field G4.

In the Advice about Voluntary Reporting section, we propose to:

• remove:
- Special nutritional products (dietary supplements, medical foods, infant formulas)
- Food (including beverages and ingredients added to foods)

• add:
- If your report involves a health problem or product problem with foods or special nutritional products such as infant formulas, dietary supplements, or medical foods, go to *https://www.safetyreporting.fda.gov* or call 1–888–723–3366 to report.

• revise:
- ''If your report involves a health problem or a product problem with a tobacco product, go to *https://www.safetyreporting.fda.gov* or call 1–877–287–1363 to report.'' to ''If your report involves a health problem or a product problem with a tobacco product, including e-cigarettes (nicotine-containing vapes) or nicotine pouches, go to *https://www.safetyreporting.fda.gov* or call 1–877–287–1363 to report.''

Changes Proposed for Form FDA 3500A

Throughout the form, we propose to:

• add calendar functionality to all date fields for uniformity and standardization of date format.

In the header, we propose to:

• revise ''For use by user-facilities, importers, distributors and manufacturers'' to ''For use by user-facilities, importers, distributors, manufacturers and packers.''

• remove the header ''FDA USE ONLY''

• revise ''Exemption/Variance #'' field to ''Exemption/Variance/Alternative #.''

In Section A, we propose to:

• based on the executive order, Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, signed by President Donald J. Trump on January 20, 2025, revise the Sex field to include two options, Male and Female. and remove the Gender field.

• combine the Ethnicity (Field A5) and Race (Field A6) fields as outlined in the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) issued on March 29, 2024. Add new text—''What is your race and/or ethnicity?'' Select all that apply.

- The data fields include:

• combine the Ethnicity (Field A5) and Race (Field A6) fields as outlined in the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) issued on March 29, 2024. Add new text—''What is your race and/or ethnicity? Select all that apply.''

- The data fields include:
  - *American Indian or Alaska Native*
  - *Asian*
  - *Black or African American*
  - *Hispanic or Latino*
  - *Middle Eastern or North African*
  - *Native Hawaiian or Pacific Islander*
  - *White*

In Section B, we propose to:

• re-order the outcomes attributed to adverse events list so that ''Other Serious or Important Medical Events'' appears as the last choice of the outcomes listed in Field B2.

• add language on page 1 ''Describe Event or Problem'' and on page 2 ''Describe Event or Problem (continued)'' (Field B5)

• add field for reference ranges in the Relevant Test/Laboratory Data section (Field B6)

In Section C, we propose to:

• revise the ''Name, Strength, Manufacturer/Compounder'' field under ''Manufacturer/Compounder Name'' '' to include a new field for ''FEI # for cosmetics'' '' This revision applies to Suspect Product #1 and Suspect Product #2. (Field C1)

• add ''Usage Dates'' after ''Treatment Dates/Therapy Dates'' and add ''Usage'' after ''treatment'' and ''Therapy.'' (Field C4)

• revise the ''Product Type'' section (Field C6) as follows (applies to Suspect Product #1 and Suspect Product #2):

- Drug or Biologic
  - Brand
  - Generic or Biosimilar
  - Over-the Counter (OTC)
  - Compounded product (by a Pharmacy or an Outsourcing Facility)
- Cosmetic
  - Cosmetic for professional use only
  - Cosmetic sold on a retail basis
- Other

In section D, we propose to interchange the fields 2a and 2b. ''Procode'' will now appear in field 2a and ''Common Device Name'' will appear in field 2b.

In Section F, we propose to:

- revise to ''User Facility or Importer Name/Address'' field to ''User Facility or Importer Name/Address/Email'' (Field F3)

• add the following two selections with checkboxes, ''Initial'' and ''Follow-up #_.'' in the Type of Report field (Field F7)

• delete ''Date of This Report (01–JAN–1900)'' field (Field F8). This information is requested in ''Report Sent to FDA?'' (Field F11) or ''Report Sent to Manufacturer?'' (Field F13).

In Section G, we propose to:

- revise ''Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility'' to ''Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility or Responsible Person'' (Field G1)
- revise ''Use Facility'' to ''User Facility'' in the Report Source field (Field G2)
- revise ''Date Received by Manufacturer (01–JAN–1900)'' to ''Date Received by Manufacturer (01–JAN–1900) or Responsible Person'' (Field G3)
- revise ''ANDA #'' to ''ANDA/Pre-ANDA #.'' (Field G4)
- revise ''Periodic'' to ''Non-expedited (periodic)'' under ''Type of Report'' field (Field G6)
- revise ''If action reported to FDA under 21 U.S.C. 360i(g), list correction/removal reporting number:'' to ''If action reported to FDA under 21 U.S.C. 360i(g), list FDA-assigned recall number or include a statement:'' (Field H9)

Changes Proposed for Form FDA 3500A Instructional Supplement

- The FDA Form 3500A instructional supplement will be revised to correct grammatical errors and to clarify reporting instructions.
- In addition to these changes, the FDA Form 3500A instructional supplement will include revisions based on the Modernization of Cosmetics Registration Act of 2022 (MoCRA). The instructional supplement will include the following revisions specifically pertaining to cosmetics:

General Instructions

- Add the text '', or cosmetic product'' to ''If no suspect medical device is involved in a reported adverse event (*i.e.,* when reporting ONLY a suspect drug or, biologic) ONLY sections A, B, C, E, and G are to be filled out:
- Remove the text ''or,'' between drug and biologic
- Add the text ''When reporting ONLY a cosmetic product, the sections and/or subsections/blocks that are not relevant to cosmetics should be left blank.''
- Add the text ''Cosmetic Products: Responsible persons submitting serious adverse event reports for cosmetic products using Form FDA 3500A should include a copy of the label on or within the retail packaging of the cosmetic product, along with any information that can be provided to support the report, such as scans of labels and images of the serious adverse event. This may be submitted to FDA:''
- Add the text ''via email at: *CosmeticAERS@fda.hhs.gov*''
- Add the text ''Or by mail to: FDA CDER Mail Center, Attn: Cosmetics MedWatch Reports. White Oak Campus, Building 22, G0207, 10903 New Hampshire Ave., Silver Spring, MD 20993''

Front Page

- Add the text ''For cosmetic products, the User Facility/Importer Report # and Exemption/Variance # should be left blank in this section.''
- Add the text ''(mfr report #): after ''Manufacturer report #''
- Revise the text ''The manufacturer report number is also entered in block G9 on the back of the form'' to ''The manufacturer report number is also entered in block G8 on the back of the form.''
- Add the text ''and for responsible persons for cosmetic products:'' to ''For drug and biologics manufacturers''
- Add the text ''that'' and ''or the responsible person to ''The ''mfr report #'' is the number the manufacturer chooses to uniquely identify the report, and should conform to any applicable regulations or guidances.''

Section B: Adverse Event or Product Problem

- B1: Type of Report
  - Adverse event: Include the text ''or cosmetic product'' to ''Any incident where the use of a product (drug or biologic, including human cell, tissue, or cellular or tissue-based product (HCT/P), at any dose, or a medical device (including in vitro diagnostic products), is suspected to have resulted in an adverse outcome in a patient.
- B2: Outcomes attributed to adverse event
- Add ''and Cosmetic Products'' to'' Drugs and Biologics''
- Include the regulatory reference ''21 CFR and Section 605 of the FD&C Act, respectively.''
- Under Disability or Permanent Damage, add the following text:
  - For cosmetic products, check if the adverse event resulted in a persistent or significant disability or incapacity.
- Under Congenital Anomaly/Birth Defect, remove the text ''medical.''
- Under Other Serious (Important Medical Events), add the following text:
  - Cosmetic Products: Check if the other categories are not applicable, such as when the adverse event results in an infection or significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance) other than as intended, under conditions of use that are customary or usual. Describe the outcomes in the actual narrative of the event in block B5.
- B4: Date of this Report
  - Add the text '', and Cosmetic Products'' to ''For all mandatory reports filed for Medical Devices, Drugs, and Biologics, including Human Cells, Tissues, and Cellular and Tissue- Based Products enter the date the report is submitted to the FDA.''
- B5: Describe Event or Problem

Add the text ''For cosmetics, please indicate whether the product was for professional use only; describe the amount and frequency used; for which body parts the cosmetic product was used; and outcomes.'' Section C: Suspect Product(s)

- Add the text ''For cosmetic products, fill out ONLY the blocks that are relevant to cosmetic products.''
- C1: Add the following text after the ''Name, Strength, Manufacturer/Compounder'' instruction—''For cosmetics: In the product name field, enter the statement of identity as such name appears on the label. If the product names in the listing are not unique, then also include distinguishing information for identification purposes. For example, please include a brand name or a code that the responsible person uses to distinguish the product. Such information may also be included, in addition to the product name, even when product names in the listing are unique. If you believe certain distinguishing information is confidential, please include that distinguishing information in parentheses''.
- C1: Add the following text after the ''NDC# or Unique ID'' instruction—''For cosmetic product(s), if available, the FDA Establishment Identifier (FEI) number obtained by the owner or operator of a facility(ies), of the facility that manufactured or processed the affected cosmetic product(s). FEI is also known as the Firm or Facility Establishment Identifier.''
- C2: List Medical Products and Treatment Given at the Same time of the Event and Date
- Add the text ''For cosmetic reports include all related cosmetic products used at the same time.''
- C3: Dose, Frequency & Route Used
- Add the text ''or the consumer'' after ''Describe how the product was used by the patient''
- Add the words ''or number of applications, area of application)'' after ''(*e.g.,* 500 mg QID orally or 10 mg every other day IV.''
- C4: Treatment/Therapy Start and Stop Dates
- Add the text ''Usage'' to the C4: Treatment/Therapy Start and Stop Dates heading

- Add the text ''treatment/therapy'' and ''or usage'' to the following sentence. ''Provide the date of administration was started (or best estimate) and the date stopped (or best estimate).''
- C6: Add the text ''Cosmetics for Professional Use Only, Cosmetics Sold on a Retail Basis,'' after ''Biosimilar,'' and before ''please check the best option that best fits this medical product.''
- C7: Add the text ''For cosmetic products, if available, include best by/use by date'' to the ''Expiration date'' after the current instruction.

Section G: All Manufacturers

- Add the text ''AND RESPONSIBLE PERSONS'' to the Section G: ALL MANUFACTURERS heading
- Add the text ''or responsible persons (in case of cosmetic products)'' to the sentence, ''This section is to be filled out by all manufacturers.''
- Add the text ''or cosmetic product'' to ''NOTE: If a drug, biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P),''
- Add the text ''(or responsible person in case of cosmetic product)'' to the ''manufacturer is reporting an adverse event in which no suspect medical device is involved, section G may be identically reproduced in place of Section D on the front of the form so that a one-page form may be submitted.''
- Add the following text, ''For cosmetic products, fill out ONLY the blocks that are relevant to cosmetic products.''
- G1: Contact Office (and manufacturing site for devices) or Compounding Outsourcing Facility
  - Add ''or Responsible Person (in case of cosmetic products)'' to ''Contact Office (and manufacturing site for devices) or Compounding Outsourcing Facility'' heading
  - Add this text as the last sentence ''For cosmetic products, enter the information of the responsible person, which means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of the cosmetic product.''
- G2: Report Source:
  - Add the text ''and Cosmetic Products'' to the sentence ''Drugs and Biologics, including HCT/Ps: A separate 3500A form must be completed for each identifiable patient described in the article or manuscript.'' Remove the text '', and'' between ''Drugs and Biologics.''
- G3: Date received by manufacturer:
  - Add the text ''or responsible person (in case of cosmetic product)'' to the heading
  - Add the text ''responsible person,'' to the following sentence, ''This means the date when the applicant, manufacturer, corporate affiliate, etc. receives information that an adverse event or medical device malfunction has occurred.''
- G6: Type of Report:
  - Under 15-day, add the following text '', and cosmetic products'' to ''As specified in the drug, biologic, including human cell, tissue, and cellular and tissue- based product (HCT/P),''
  - Under 15-day, add the following text ''or requirements,'' to ''regulations for reports of serious and unexpected adverse events.''
  - Change the ''Periodic'' label to ''Non-expedited (Periodic)'' and add ''For Cosmetic products, use this option for non-serious adverse event.''
  - Under Follow-up, add the text ''and cosmetic products'' to ''Follow-up reports on drugs, biologics, including HCT/Ps, should contain information that was submitted in the original report if the information is still correct.''
- G7: Adverse Event Term(s):
  - Add the text '', and cosmetic products'' to ''[for use by drug, biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P),''
  - Add the text ''(or responsible persons, in case of cosmetic products)'' to ''manufacturers only]''
  - Remove the text ''or WHOART'' from the list of accepted standards.
- G8: Manufacturer Report Number
  - Remove the following text that refers to the MedWatch to Manufacturer program. ''If submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer program transmission of a serious direct report, check the ''Other'' box in block G2 and enter the FDA-assigned report number there.''
  - Add ''For cosmetics: The manufacturer report number is the number the responsible person chooses to uniquely identify the report, and should conform to any applicable regulations or guidances. The submission will not be considered complete without this information. While FDA currently does not have a mandatory format for the Manufacturer Report Number for reporting cosmetic adverse events, we strongly encourage you to use a numbering system that provides unique information of the adverse event reported, such as the year, company name, and the case report number.

Changes Proposed for Form FDA 3500B

In the instructions section, we propose to make the following revisions:

- Under ''When do I use this form?''
  - Revise the first bullet to ''You were hurt or had a bad side effect (including new or worsening symptoms) after taking a drug or using a medical device or product to ''You were hurt or had a bad side effect (including new or worsening symptoms) after using a product, drug, cosmetic or a medical device.''
  - Add the word ''cosmetic'' after the word ''drug'' in the following bullets:
    - You used a product, drug, cosmetic, or medical device incorrectly which could have or led to unsafe use.
    - You noticed a problem with the quality of the product, drug, cosmetic, or medical device.
- Under ''Don't use this form to report:''
  - Add the hyperlink for the Vaccine Adverse Event Reporting System (VAERS), add descriptive language under tobacco products about e-cigarettes and nicotine pouches, remove the word cosmetic from the safety reporting portal language and revise the hyperlink to the Safety Reporting Portal.
  - Vaccines—report problems to the Vaccine Adverse Event Reporting System (VAERS) *http://vaers.hhs.gov.*
  - Tobacco products, including e-cigarettes (nicotine-containing vapes) and nicotine pouches—report health or product problems to the Safety Reporting Portal (SRP) *https://www.safetyreporting.fda.gov/* or call 1–877–287–1363.
  - Remove the word ''cosmetic'' from the last bullet—Food or dietary supplement products—report problems to the SRP *https://www.safetyreporting.fda.gov/.*
- Under ''What types of products should I use this form for?''
  - In the first bullet, add a comma between ''bone), allergenics''
  - In the third bullet, remove the word ''makeup.''
  - Add bullet for ''Cannabinoid Hemp Products (such as products containing CBD''
  - Remove last bullet: Foods (including beverages and ingredients added to foods)
- Under ''Are there specific instructions for filling out the form?''
  - The first two bullets in this section will remain unchanged.
  - New text will be added for the third and fourth bullet.
    - Including or attaching images of all sides of the product will help FDA review your report but is not required. Please do not send the products to the FDA.
    - The Global Unique Device Identification Database (GUDID) contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI). In

collaboration with the National Library of Medicine, the FDA has created a portal, called Access GUDID, to make device identification information in the GUDID available for everyone. For more information regarding the UDI#, refer to the UDI web page, *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.*

- Under ''How can I contact the FDA if I have questions?'' add a phone number for cosmetics.
  - For Cosmetics: Toll-free line: 1–888–723–3366
- Add language to match that of the MedWatch Online application
  - If this is a medical emergency, please call 911.
  - If you have a mental health crisis, please call 988.

In Section A—About the Problem, we propose to:

- Add field for reference ranges in the Relevant Test/Laboratory Data section (Field A5)

In Section B—Product Availability, we propose to:

- Revise the question in Field B2 from ''Do you have a picture of the product? (check yes if you are including a picture)'' to ''2. Do you have a picture of the product including product labels if reporting cosmetics? While not required, pictures of all sides of the product will help FDA review your report. (check yes if you are including pictures)
- Under the section, ''For a problem with a product, including''
  - Remove the language ''or make-up products'' from the fourth bullet.
  - Remove bullets 3 and 5:
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- foods (including beverages and ingredients added to foods)
- Under the section ''For a health or product problem with a food, cosmetic, dietary supplement or tobacco product''
  - Remove the word ''cosmetic.''
  - Revise the hyperlink to the Safety Reporting Portal to *https://www.safetyreporting.fda.gov/*

In Section C: About the Products, we propose to:

- Remove ''This report is about'' or field C1. Product type field will be updated.
- Add a section for a second suspect product and design the two sections for suspect product on the same page to facilitate the addition of another page if the reporter needs to report more than two products.
- For field C3, add the word ''usage'' after ''therapy.'' Revised language will be ''Check if therapy/usage is on-going.''
- Revise the field ''Product Type'' (Field C5) as follows: (Note: Dietary supplement and Food/Medical Food selections will be removed. Adverse events involving these products should be submitted through the Safety Reporting Portal)
  - Drug or Biologic
    - Brand
    - Generic or Biosimilar
    - Over-the Counter (OTC)
    - Compounded product (by a Pharmacy or an Outsourcing Facility)
  - Cosmetic
    - Cosmetic for professional use only
    - Cosmetic sold on a retail basis
  - Cannabinoid Hemp Products (such as products containing CBD
  - Other
- For Field C12, revise instructions from ''How was it taken or used (for example, by mouth, injection, or on the skin)?'' to ''How was it taken or used (for example, by mouth, injection, inhaled, or on the skin)?'' to add the word ''inhaled.''
- Add a field for ''Purchase Date.''
- Add a field for Where (*e.g.,* website, pharmacy/store/state of purchase) was the suspect product obtained and When (date) was the suspect product obtained. Propose addition of fields to capture ''Place of Purchase Name,'' ''web page/URL (if purchased online),'' and ''Place of Purchase City and State/Province''

Under Section D—About the Medical Device, we propose to:

- For field D7, add Text to read as ''Unique Device Identifier (UDI) number—Please record all symbols, letters and numbers located under the barcode. An example of a UDI number can be found at *https://accessgudid.nlm.nih.gov/about-gudid#what-is-udi.*''

Under Section E—About the Person Who Had the Problem, we propose to:

- based on the executive order, Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, signed by President Donald J. Trump on January 20, 2025, revise the Sex field to include two options, Male and Female. and remove the Gender field.
- Add calendar functionality to Field E4 (Date of Birth) for uniformity in reporting and to ensure correct reporting of date format.
  - Combine the Ethnicity (Field E6) and Race (Field E7) fields as outlined in the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) issued on March 29, 2024. Add new text—''What is your race and/or ethnicity? Select all that apply.'' The data fields include:
    - *American Indian or Alaska Native*
    - *Asian*
    - *Black or African American*
    - *Hispanic or Latino*
    - *Middle Eastern or North African*
    - *Native Hawaiian or Pacific Islander*
    - *White*

Under Section F—About the Person Filling Out This Form, we propose to:

- For Field F4, change the title of the field from ''City and State/Province'' to ''City and State/Province (including your State/Province will help FDA review your report).''

Under ''Send This Report by Mail or Fax,'' revise the mailing address to Attn: MedWatch Program, White Oak Campus, Building 22, G0207, 10903 New Hampshire Ave., Silver Spring, MD 20993.

Changes Proposed for Form FDA 3800, Safety Reporting Portal

The Center for Tobacco Products (CTP) proposes to make non-substantive changes to the Tobacco Product Report (TPR) and Tobacco Investigator Report (TIR) questionnaires in the Safety Reporting Portal. The proposed changes clarify the instructions, clarify existing questions, and simplify certain response fields.

CTP also proposes to modify the instructions in response to findings in a user experience study that was completed in 2024. For example, participants wanted the instructions to indicate how long the report typically takes to complete. CTP proposes to replace some structured answer lists with free text boxes to shorten the questionnaire and better align with the MedWatch forms. CTP proposes to remove structured answer choices that have been rarely or never used, while maintaining the current functionality that allows uncommon responses to be provided in free-text boxes. CTP proposes to replace certain free-text or structured answer choices with searchable drop-down menus to assist in answer selection.

The proposed changes do not change the breadth or depth of data collected in the questionnaires or the number of required questions. The proposed changes aim to reduce the burden on the reporter by shortening the questionnaire and streamlining the questions and instructions. The proposed changes are supported by the results of a user experience study that was completed in 2024.

In the **Federal Register** of January 17, 2025 (90 FR 5900), we published a 60-day notice soliciting public comment on the proposed collection of information.

Two comments were received supporting FDA's addition of a ''cannabinoid hemp product'' category for reporting adverse events, but encouraged FDA to include additional categories as well that would allow for specific data as it pertained to a wider variety of individual products. A third comment was received encouraging the enhancement of FDA's MAUDE system using automated technologies that would allow for easier input by respondents. FDA appreciates each comment and although we continue to modify applicable forms to increase the utility of the information collection as our limited resources allow, we are proposing no other modifications at this time and have made no changes in the estimated burden based on these public comments.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center or 21 CFR Section and/or FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CBER/CDER, FDA 3500 (voluntary reporting)	58,711	1	58,711	0.66 (40 minutes)	38,749
CBER, FDA 3500A; 600.80; 1271.350 (mandatory reporting)	599	98	58,702	1.21	71,029
CBER, FDA 3500B	13,750	1	13,750	0.46 (28 minutes)	6,325
CDER, FDA 3500B	18,961	1	18,961	0.46 (28 minutes)	8,722
CDRH, FDA 3500 and FDA 3500B	15,304	1	15,304	0.46 (28 minutes)	7,040
CTP, FDA 3500	39	1	39	0.66 (40 minutes)	26
HFP, FDA 3500	7,442	1.061	7,895	0.66 (40 minutes)	5,211
HFP, FDA 3500A	1,659	1	1,659	1.21	2,007
Written requests for temporary waiver under § 329.100(c)(2)	1	1	1	1	1
Total					139,110

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
CBER—Center for Biologics Evaluation and Research.
CDER—Center for Drug Evaluation and Research.
CDRH—Center for Devices and Radiological Health.
HFP—Human Foods Program.
CTP—Center for Tobacco Products.

The estimates in Table 1 are based on current agency data and our experience with the information collection.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN E-SUBMISSIONS INCLUDING VIA SRP [1]

FDA Form 3800	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reportable Foods Registry (mandatory reports)	875	1	875	0.6 (36 minutes)	525
Reportable Foods Registry (voluntary reports)	5	1	5	0.6 (36 minutes)	3
Food, Infant Formula, and Cosmetic Adverse Event Reports	1,165	1.2	1,398	0.6 (36 minutes)	839
Voluntary Dietary Supplement Adverse Event Reports	360	1.2	432	0.6 (36 minutes)	259
Mandatory Dietary Supplement Adverse Event Reports	80	12	960	1	960
Animal Food: Voluntary Pet Food Reports	1,401	1	1,401	0.6 (36 minutes)	841
Animal Food: Voluntary Livestock Food Reports	23	1	23	0.6 (36 minutes)	14
Voluntary Tobacco Product Health Problem or Product Problem (*i.e.,* adverse experience) Reports to SRP (both questionnaires)	176	1	176	0.6 (36 minutes)	106
Mandatory Tobacco Product Health Problem or Product Problem (*i.e.,* adverse experience) Reports 1114.41(a)(2)	3	6	18	0.6 (36 minutes)	11

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN E-SUBMISSIONS INCLUDING VIA SRP [1]—Continued

FDA Form 3800	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total			5,924		3,961

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents for the Voluntary Tobacco Product Health Problem or Product Problem Reports e-submissions has decreased from 204 to 176, according to an updated analysis.

Based on burden estimates associated with the Premarket Tobacco Product applications and Recordkeeping Requirements regulation we have decreased the average burden per response from 1 hour to 36 minutes for 1114.41(a)(2); Mandatory Tobacco Product Health Problem or Product Problem Reports.

CVM reports a decrease in the number of submissions received over the last few years.

CDER/CBER has increased the number of direct safety reports from healthcare providers and consumers. Additionally, CDER mandatory reports, Form FDA 3500A previously included in this information collection, are now reported in the approved information collection, OMB control number 0910–0230. However, increases in receipts of CBER mandatory reports have obscured any decrease in burden. Adverse event reports related 21 CFR 310.305 from outsourcing facilities are also included in 0910–0230 and decreases the total burden of this collection.

Based on updated data, CDRH has revised our estimate for forms FDA 3500 and FDA 3500B. Additionally, we have determined that the estimate previously reported in this information collection for mandatory reporting under 21 CFR part 803, associated with medical device products, using form FDA 3500A, is redundant with our approved burden estimates in OMB control number 0910–0437 *Medical Device Reporting* (under 21 CFR part 803). We have therefore removed CDRH reporting via FDA 3500A from this information collection request and continue to account for its burden in OMB control number 0910–0437.

Based on agency experience HFP's estimated burden for the information collection reflects an overall increase. We attribute this adjustment to an increase in the number of submissions we received over the last few years, due primarily to changes in the infant formula industry.

Therefore, the cumulative changes, both program changes which include form revisions, and adjustments reflecting fluctuations in submissions, as well as removing double-counted burden reflects and overall increase of 116,014 hours to the total burden for this information collection.

Dated: June 18, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11605 Filed 6–24–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Data System for Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 25, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0915–0157—Revision.

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by award, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under oversight of the HRSA, operates the U.S. Organ Procurement and Transplantation system. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits OPTN Board of Directors (BOD)-approved data elements for collection to OMB for approval.

A 60-day notice was published in the **Federal Register** on November 1, 2024, Vol. 89, No. 212, pp. 87380–85. There were six comments, including feedback from OPTN Members and Transplant Centers. Public comments raised concerns about the financial burden of additional data collection. The commenters called for greater collaboration between transplant professionals, HRSA, and the Scientific Registry of Transplant Recipients to eliminate redundancies and improve efficiency. Commenters expressed concern that changes were communicated via the **Federal Register** instead of the OPTN public comment process, limiting input from the transplant community. Additionally, the commenters sought clarification on discrepancies regarding which forms were designated as new, and they requested access to the data collection plans and draft instruments.

HRSA carefully reviewed all public feedback submitted during the 60-day comment period. Through its policy development process, OPTN had previously solicited input on each of the data collection instruments through four channels:

(1) Targeted outreach to relevant stakeholder organizations, including